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November 15, 2001

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

APPLICATION FOR EXEMPTION

Dear Sir/Madam:

Re: Minoxidil Topical Solution USP 5%
ANDA No. 75-839
Docket No. 98N-0337 APPLICATION FOR EXEMPTION

Statement of Purpose

Pursuant to 21 CFR 201.66(e), Novex Pharma hereby requests an exemption from 21 CFR 201.66(c) and (d) in the form of a temporary deferral of the implementation of the requirements of this regulation. This deferral is requested because there is not currently approved reference listed drug labeling in Drug Facts format (DFL) or an Office of Generic Drugs DFL template for 5% minoxidil topical solution products. The exemption would apply to all current and future SKUs of this drug product.

The reference listed drug for this ANDA is Rogaine® Extra Strength (For Men) (NDA No. 20-834).

Background of the Request

For the 5% minoxidil products, there is not currently approved labeling for the reference listed drug in DFL format or an OGD template. Therefore, in order to ensure continuing compliance with both the statue and the regulation, a temporary deferral of the implementation date is required until approved reference listed drug labeling or a FDA template is available in Drug Facts format.

In a letter from Dr. Charles Ganley to the Consumer Healthcare Products Association dated August 9, 1999, it was recommended that ANDA holders submit a request for deferral in those cases where the reference listed drug has not received approval for labeling in the Drug Facts format in sufficient time to allow conversion of the ANDA product labeling by the regulatory compliance date.

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Drugs Approved After April 16, 1999

The final rule, published on March 17, 1999, states that OTC ANDA drug products approved after April 16, 1999, must meet the requirements of part 201.66 immediately upon approval. However, the Office of Generic drugs has continued to approve ANDAs after April 16, 1999, without labeling that complies with section 201.66 and without comment as to the need to meet the requirements.

This drug product was approved on October 1, 2001. However, as of the date of this request, there is not approved reference listed drug labeling in DFL or an OGD template to follow.

Our understanding is that, in the case where an ANDA for an OTC drug product is approved after April 16, 1999, without Drug Facts labeling, that product may be marketed with labeling approved in the ANDA. When approved reference listed drug labeling or an OGD template in DFL becomes available to the ANDA applicant, the product labeling should then be updated with appropriate notice to the application.

Length of the Deferral Request

At the time that approved DFL format labeling becomes available (either by the reference listed drug or an OGD template), a Changes Being Effected supplement for approval of the new labeling in the DFL format will be filed. Due to the length of time required to prepare labeling, submit a CBE supplement, and finally convert the labeling of a product, we anticipate that conversion for this product can be accomplished within approximately six months from the filing of the supplement, assuming that there are no changes required following OGD review.

For Minoxidil Topical Solution 5%, we request the following schedule of deferrals based upon the date of availability of the final DFL template or approved reference listed drug labeling:

Final DFL Template (or RLD Labeling) Issued for the Product	**Deferral Requested**
11/01/2001 to 11/30/2001	Deferral of 60 days
12/01/2001 to 12/31/2001	Deferral of 90 days
01/01/2002 to 01/31/2002	Deferral of 120 days
02/01/2002 to 02/28/2002	Deferral of 150 days
03/01/2002 to 03/31/2002	Deferral of 180 days
04/01/2002 to 04/30/2002	Deferral of 210 days
05/01/2002 to 05/31/2002	Deferral of 240 days

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This schedule of requested deferrals is necessary because of the uncertain timing of the issuance of the final DFL template or approved reference listed drug labeling and the certain compliance date of May 2002.

Should you require any further information, or have any questions or comments regarding the enclosed, please do no hesitate to contact me directly at (905) 508-2562 or FAX your requests to (905) 884-0357.

Yours sincerely,

for Dawn Culp, B. Sc.
Manager, Regulatory Affairs

cc:
Gary Buehler, Director
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